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SAFETY EVALUATION OF VASCULAR CLOSURE DEVICES IN FEMORAL ARTERY ACCESS

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Objective The aim of the study was to evaluate the in-hospital and long term safety performance of vascular closure devices (VCDs) in femoral artery access.

Methods One thousand and seventy eight patients who undergoing transfemoral percutaneous cardiac catheterisations from June 2008 to October 2009 were enrolled. We compared the incidence of in-hospital vascular complications between manual compression group and VCDs group. Femoroiliac angiographic data were collected and analysed on 92 patients undergoing repeat catheterisation via ipsilateral femoral artery for which VCDs have been used for at least 3 month during index transfemoral catheterisation. The percent diameter stenosis (Δ DS%) was utilised to evaluate the long-term safety performance of vascular closure devices on femoral angiogram. Restenosis of femoral artery was defined as Δ DS% $\geq$ 50%.

Results The overall in-hospital incidence of vascular complication was 0.74% (8/1078). Patients in VCDs group had relatively lower rate of in-hospital complications ($p=0.039$) compared with manual compression group. The median interval of femoral angiogram recheck was 232 days. Femoral restenosis at the site of vascular access occurred in 3.3% of 92 patients, but no one had complaints of limb ischemia.

Conclusions VCDs demonstrated greater in-hospital and long-term safety performance compared with manual compression. Femoral restenosis at puncture site is very rare and usually asymptomatic.